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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,036	08/03/2000	Pravin T.P. Kaumaya	18525-04011	9722

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CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER
RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	30

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/632,036	Applicant(s) KAUMAYA ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003 and 22 May 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,11-22 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-9,11-22 and 25-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election facsimile cover sheet* .

DETAILED ACTION

1. The response filed March 26, 2003 in Paper No. 27 is acknowledged and has been entered.

2. The amendment filed May 22, 2003 in Paper No. 29 is acknowledged and has been entered.

3. The restriction and election requirement set forth in the Office action mailed October 2, 2002 in Paper No. 20 is hereby vacated. The Examiner regrets any inconvenience this decision may cause Applicants.

4. Claims 1, 3-9, 11-22, and 25-33 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1, 3-9, 11-20, and 31, insofar as the claims are drawn to a composition comprising a chimeric peptide, wherein said chimeric peptide may comprise one or more HER-2 B cell epitopes, wherein said HER-2 B cell epitopes are selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, and SEQ ID NO: 42, one or more HER-2 CTL epitopes, wherein said HER-2 CTL epitopes are selected from those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO:

37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41, a T helper epitope, and a linker, classified in class 424, subclass 185.1.

Note: In reply to this Office action, if Applicants wish elect one of the inventions encompassed by the grouping of claims 1, 3-9, 11-20, and 31, Applicants are required to do so by specifically identifying the chimeric peptide to which the claims are to be drawn; the chimeric peptide may consist of one or more of the HER-2 B cell epitopes selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, and SEQ ID NO: 42 and/or one or more of the HER-2 CTL epitopes selected from those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41. For example, Applicants might wish to elect the invention of claims 1, 3-9, 11-20, and 31, insofar as the claims are drawn to a composition comprising a chimeric peptide that comprises SEQ ID NO: 1 and SEQ ID NO: 21, or as another example, the invention of claims 1, 3-9, 11-20, and 31, insofar as the claims are drawn to a composition comprising a chimeric peptide comprising SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 22.

Claims 21 and 22, insofar as the claims are drawn to a method for stimulating an immune response in a subject comprising administering to the subject a chimeric peptide, which may comprise one or more HER-2 B cell epitopes, wherein said HER-2 B cell epitopes are selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID

NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, and SEQ ID NO: 42, one or more HER-2 CTL epitopes, wherein said HER-2 CTL epitopes are selected from those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41, a T helper epitope, and a linker, classified in class 424, subclass 185.1.

Note: In reply to this Office action, if Applicants wish elect one of the inventions encompassed by the grouping of claims 21 and 22, Applicants are required to do so by specifically identifying the chimeric peptide to which the claims are to be drawn; the chimeric peptide may consist of one or more of the HER-2 B cell epitopes selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, and SEQ ID NO: 42 and/or one or more of the HER-2 CTL epitopes selected from those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41. For example, Applicants might wish to elect the invention of claims 21 and 22, insofar as the claims are drawn to a method comprising administering to a subject a chimeric peptide that comprises SEQ ID NO: 1 and SEQ ID NO: 21, or as another example, the invention of claims 21 and 22, insofar as the claims are drawn to a method comprising

administering to a subject a chimeric peptide comprising SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 22.

Claims 25-29, insofar as the claims are drawn to a method for treating cancer in a subject comprising administering to the subject a pharmaceutical composition comprising a chimeric peptide, wherein said chimeric peptide comprises a HER-2 B cell epitope selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 9, SEQ ID NO: 10, and SEQ ID NO: 11, a T helper epitope, and a linker, classified in class 514, subclass 2.

Note: In reply to this Office action, if Applicants wish elect one of the inventions encompassed by the grouping of claims 25-29, Applicants are required to do so by specifically identifying the chimeric peptide to which the claims are to be drawn; the chimeric peptide may consist of a HER-2 B cell epitope selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 9, SEQ ID NO: 10, and SEQ ID NO: 11. For example, Applicants might wish to elect the invention of claims 25-29, insofar as the claims are drawn to a method comprising administering to a subject a pharmaceutical composition comprising a chimeric peptide that comprises SEQ ID NO: 1.

Claims 25-29, insofar as the claims are drawn to a method for treating cancer in a subject comprising administering to the subject a pharmaceutical composition comprising a chimeric peptide, wherein said chimeric peptide comprises a HER-2 CTL epitope selected from those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO:

38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41, a T helper epitope, and a linker, classified in class 514, subclass 2.

Note: In reply to this Office action, if Applicants wish elect one of the inventions encompassed by the grouping of claims 25-29, Applicants are required to do so by specifically identifying the chimeric peptide to which the claims are to be drawn; the chimeric peptide may consist of a HER-2 CTL epitope selected from the group consisting those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41. For example, Applicants might wish to elect the invention of claims 25-29, insofar as the claims are drawn to a method comprising administering to a subject a pharmaceutical composition comprising a chimeric peptide that comprises SEQ ID NO: 21.

Claim 30, insofar as the claim is drawn to a polynucleotide encoding a chimeric peptide, wherein said chimeric peptide comprises a HER-2 CTL epitope selected from those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41, a T helper epitope, and a linker, classified in class 514, subclass 2.

Note: In reply to this Office action, if Applicants wish elect one of the inventions encompassed by claim 30, Applicants are required to do so by

specifically identifying the chimeric peptide to which the claims are to be drawn; the chimeric peptide may consist of a HER-2 CTL epitope selected from the group consisting those set forth as SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 36, SEQ ID NO: 37, SEQ ID NO: 38, SEQ ID NO: 39, SEQ ID NO: 40, and SEQ ID NO: 41. For example, Applicants might wish to elect the invention of claim 30, insofar as the claim is drawn to a polynucleotide encoding a chimeric peptide that comprises SEQ ID NO: 21.

Claims 32 and 33, insofar as the claims are drawn to a method for treating cancer in a subject comprising administering to the subject a mixture of two or more chimeric peptides, wherein said chimeric peptides each comprise a different HER-2 B cell epitope selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, and SEQ ID NO: 42, a T helper epitope, and a linker, classified in class 514, subclass 2.

Note: In reply to this Office action, if Applicants wish elect one of the inventions encompassed by claims 32 and 33, Applicants are required to do so by specifically identifying the mixture of chimeric peptides to which the claims are to be drawn; the mixture of chimeric peptides may comprise two or more chimeric peptides, each comprising a different HER-2 B cell epitope selected from the group consisting those set forth as SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10,

SEQ ID NO: 11, SEQ ID NO: 12, and SEQ ID NO: 42. For example, Applicants might wish to elect the invention of claims 32 and 33, insofar as the claims are drawn to a method comprising administering to a subject a mixture comprising a chimeric peptide comprising SEQ ID NO: 1 and a chimeric peptide comprising SEQ ID NO: 2.

6. The inventions are distinct, each from the other because of the following reasons:

The inventions in the grouping of claims 1, 3-9, 11-20, 30, and 31 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions in the groupings of claims 21 and 22, claims 25-29, and claims 32 and 33 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

Inventions of the grouping of claims 1, 3-9, 11-20, and 31 and the inventions of the grouping of claims 21 and 22, the grouping of claims 25-29, and the grouping of claims 32 and 33 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely a composition comprising one or more chimeric peptides can be used in a materially different process of using that product, namely one or the other of the methods as claimed in the groupings of claims 21 and 22, claims 25-29, and claims 32 and 33.

The inventions encompassed by claims 30 and the inventions of the groupings of claims 21 and 22, claims 25-29, and claims 32 and 33 are not at all related because the products of claim 30 are not specifically used in any of the steps of the claimed methods in claims 21 and 22, claims 25-29, or claims 32 and 33.

7. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Claims 1, 3-9, 11-22, and 25-33 are further subject to the following restrictions of patentably distinct species of invention:

Claims 1, 3-9, 11-22, and 25-33 are generic to a plurality of disclosed patentably distinct species of invention wherein said T helper epitope is selected from those set forth as SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, and SEQ ID NO: 18. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 25 is generic to a plurality of disclosed patentably distinct species of invention wherein said cancer is selected from the group consisting of breast cancer, ovarian cancer, lung cancer, prostate cancer, and colon cancer. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 25 is generic to a plurality of disclosed patentably distinct species of invention wherein said vehicle is selected from the group consisting of an emulsion and a microsphere or nanosphere. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 27 is generic to a plurality of disclosed patentably distinct species of invention wherein said oil is selected from the group consisting of squalene and squalane. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

9. Should Applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

S Rawlings
STEPHEN RAWLINGS

slr
August 5, 2003

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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